R.126 12

23. The system as defined in Claim 15, further including means for circulating said perfusate from said biological entity to said oxygenator.

R.126 13

24. The system as defined in Claim 23, further including at least one access port in said means for circulating said perfusate.

R.126 A1 contd 14

25. The system as defined in Claim 24, wherein said at least one access port permits the addition of drugs or pharmaceutical agents.

R.126 15

26. The system as defined in Claim 24, wherein said at least one access port permits the extraction of a quantity of said perfusate.

SubC1 R.126 16

27. The system as defined in Claim 24, wherein said at least one access port permits the addition of a quantity of said perfusate.

REMARKS

1. **The 35 U.S.C. 112, Second Paragraph Rejection**

Claims 2-14 are pending in the application. The Examiner has rejected Claims 2 through 14 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, with such omission amounting to a gap between the necessary structural connections.

2. **Response to the 35 U.S.C. 112, Second Paragraph Rejection**

The pending Claims have been cancelled and new Claims have been added in order to clarify essential structural cooperative relationships of elements and necessary structural connections within the scope of the disclosure of the present invention. Applicant would like to emphasize that the amendments to the Claims are made in order to overcome the 35 U.S.C. 112,

second paragraph rejection and not the 35 U.S.C. 102(b) rejections. Applicant believes that limitations already present in the Claims distinguish the present invention over the cited references as argued more fully below. Accordingly, the Applicant has more particularly pointed out and distinctly claimed the subject matter which the Applicant regards as his invention and the 35 U.S.C. 112, second paragraph rejection has been traversed.

3. **The 35 U.S.C. §102 (b) Rejections**

The Examiner has rejected Claim 2-14 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,837,390 issued on June 6, 1989 to **Reneau**. Additionally, Claims 2,4,5, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,356,771 issued on October 18, 1994 to **O'Dell**.

4. **Response to the 35 U.S.C. §102 (b) Rejection Based on Reneau**

The **Reneau** patent describes a hyperbaric oxygen preservation apparatus and method for preserving living organs. The apparatus includes a perfusate reservoir which is maintained at ambient pressure, with the organ preservation chamber maintained at the desired elevated pressure. The key feature of **Reneau** is the ability to modify the perfusate without depressurizing the apparatus (column 1, lines 65-68).

Reneau teaches the introduction of perfusate and pressurized oxygen into the hyperbaric chamber without the benefit of an oxygenator. In contrast, the present invention teaches a system wherein a high surface area oxygenator within the pressurized vessel greatly increases the relative surface area between the fluid and the oxygen, thus quickly and more thoroughly oxygenating the perfusate.

Moreover, **Reneau** relies solely upon passive diffusion of oxygen and nutrients from the surface of the biological entity through immersion in the perfusate. Quite distinctly, the present invention claims active perfusion of the biological entity through the pumping of the hyper-oxygenated perfusate throughout the vasculature of the biological entity. In the present invention, the pressure differential between the chamber and the return vasculature facilitates the removal and active transport of the perfusate out of the vessel, thus mimicking normal blood circulation.

Thus, **Reneau** does not teach high surface area oxygenation, active perfusion via the vasculature of the biological entity, nor recirculation of perfusate through an active transport pressure differential.

5. **Response to the 35 U.S.C. §102 (b) Rejection Based on O'Dell**

The **O'Dell** patent describes a combined perfusion and oxygenation organ preservation apparatus. The device utilizes a gas permeable membrane to introduce oxygen into a perfusate container and thereby to pump perfusate from a first container through a one-way inlet port valve and through inlet tubing into the organ tissue in a second container (column 3, lines 27-45). The perfusate is oxygenated through the membrane at near ambient pressure. After the pressure cycle, the one-way valve in the outlet port opens, allowing the pressure to equalize between the two compartments. The outlet port is not directly connected to the organ tissue, but simply connects the two containers for pressure equalization. This allows a free flow of perfusate from the second container, i.e., tissue compartment, back into the first container, i.e., perfusing compartment. The pressure therefore returns to ambient pressure in the completion of the cycle, thus minimizing any true hyperbaric forces.

In contrast, the present invention operates at a pressure of about 2280 mmHg, which pressure is maintained throughout operation. Moreover, the present invention utilizes fluid delivery tubing which not only connects the oxygenator to the biological entity, but which also directly connects the biological entity to the perfusate container for the return flow. Specifically, the fluid delivery tube which connects the oxygenator to the biological entity typically cannulates the arterial vessel and the fluid delivery tube which carries perfusate from the biological entity to the perfusate container cannulates the vein of the biological entity.

Thus, the perfusate pathway of the present invention mimics natural circulation: reducing tissue injury risk while maximizing tissue perfusion. Only in those rare instances where the biological entity does not have an artery or vein is the fluid delivery tube of the present invention open to the organ container in which the biological entity is submerged. In that case, the fluid delivery tube is open near the bottom of the organ container for perfusate to be returned to the perfusate container. Additionally, the present invention utilizes a biological filter to remove impurities from the circulatory pathway rather than simply recirculating such biological impurities into the perfusate container.

CONCLUSION

Thus, Applicant has addressed each of the Examiner's rejections by modifying the claims to properly demonstrate all structural cooperative relationships and setting forth the novel features of the present invention which clearly distinguish it from the cited references.

As all claims have now been clarified, they are in a condition for allowance. Such action upon reconsideration by the Examiner is earnestly solicited. It is respectfully requested that upon reconsideration the Examiner issue a notice of allowance. Should the Examiner feel that

the prosecution of the above-identified application may be materially advanced by a telephone call, the Examiner is hereby requested to call the undersigned.

Respectfully submitted,
COX & SMITH INCORPORATED

Date: 10/11/02

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Certificate of Mailing

I hereby certify that this paper and/or fee and all documents indicated as being attached are being deposited with the United States Postal Service on the date indicated below with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.
Date of Deposit: October 11, 2002

Carol A. Hamann

Carol A. Hamann

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 2-14 have been cancelled.

New Claims 15-27 have been added as follows:

15. A system for supplying hyperbaric oxygen to a biological entity, said system comprising:

a vessel capable of receiving and maintaining said hyperbaric oxygen and enclosing said biological entity;

a pressurized gas source for supplying said hyperbaric oxygen;

an oxygenator for receiving said hyperbaric oxygen;

a perfusate for absorbing said hyperbaric oxygen within said oxygenator; and

a fluid delivery tube attached to said oxygenator;

whereby oxygenated perfusate is delivered to said biological entity through said fluid delivery tube.

16. The system as defined in Claim 15, further including a metabolic supplement, whereby said metabolic supplement is added to said perfusate for delivery to said biological entity.

17. The system as defined in Claim 16, further including means for monitoring the effect of said metabolic supplement on said biological entity.

18. The system as defined in Claim 15, wherein said oxygenated perfusate contains at least 4.5 volume percent oxygen.

19. The system as defined in Claim 15, further including a temperature control unit whereby the temperature of said perfusate and said biological entity can be regulated from approximately 0 degrees centigrade to approximately 40 degrees centigrade.

20. The system as defined in Claim 15, wherein said perfusate contains biological entity waste products and said system further comprises a biological filter for removal of said biological entity waste products.

21. The system as defined in Claim 15, further including a perfusate container for holding said biological entity and a quantity of said perfusate within said vessel.

22. The system as defined in Claim 15, further including means for pumping said perfusate.

23. The system as defined in Claim 15, further including means for circulating said perfusate from said biological entity to said oxygenator.

24. The system as defined in Claim 23, further including at least one access port in said means for circulating said perfusate.

25. The system as defined in Claim 24, wherein said at least one access port permits the addition of drugs or pharmaceutical agents.

26. The system as defined in Claim 24, wherein said at least one access port permits the extraction of a quantity of said perfusate.

27. The system as defined in Claim 24, wherein said at least one access port permits the addition of a quantity of said perfusate.